



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,350	08/13/2002	Guillaume Jean Hervieu	P32320	3095

20462 7590 05/17/2004

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER

HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,350

Applicant(s)

HERVIEU ET AL.

Examiner

Zachary C Howard

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 14-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. Claims 14-29 are pending in the instant application.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 14-21, in so far as they are drawn to methods of treatment by administration of an h-TREK polypeptide.

Group II, claim(s) 14-19 and 23, in so far as they are drawn to methods of treatment by administration of compounds that activate an h-TREK polypeptide.

Group III, claim(s) 14-19 and 22, in so far as they are drawn to methods of treatment by administration of compounds that inhibit an h-TREK polypeptide.

Group IV, claim(s) 14-19 and 24-26, in so far as they are drawn to gene therapy.

Group V, claim(s) 27-29, in so far as they are drawn to in vitro methods of screening to identify a compound useful in treatment of recited conditions comprising contacting said compound with an h-TREK polypeptide.

Art Unit: 1646

Group VI claim(s) 27-29, in so far as they are drawn to in vivo methods of screening to identify a compound useful in treatment of recited conditions comprising contacting said compound with an h-TREK polypeptide.

3. The inventions listed as Groups I, II, III, IV, V, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the methods of treatment require either administration of a protein; compounds that activate or inhibit the protein; or gene therapy, each of which requires administration of different compounds which are structurally and functionally different from each other and each of which can be made and used without the other, and steps and methods of the groups are different. The in vitro and in vivo methods of Group V and Group VI are functionally different from groups I-IV and each other, and each method can be performed independently of the other methods. Lack of unity is shown because these compounds, or method steps, lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Election of species:

In addition to the above restriction requirement, a further election of species is required as follows:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Methods of treatment of the conditions of epilepsy, sleep-related disorders, cognitive dysfunction, attention deficit disorder, addiction, anxiety, phobia, dyskinesias,

Art Unit: 1646

Parkinson's Disease, Huntington's chorea, cerebral palsy, incontinence, erectile dysfunction and alopecia.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

1. Claims 14, 15 and 20-29 correspond to the condition of epilepsy.
2. Claims 14, 16, 17 and 20-29 correspond to the condition of sleep-related disorders.
3. Claims 14, 18 and 20-29 correspond to the condition of cognitive dysfunction.
4. Claims 14 and 20-29 correspond to the condition of attention deficit disorder.
5. Claims 14 and 20-29 correspond to the condition of addiction.
6. Claims 14 and 20-29 correspond to the condition of anxiety.
7. Claims 14 and 20-29 correspond to the condition of phobia.
8. Claims 14, 19 and 20-29 correspond to the condition of dyskinesias.
9. Claims 14, 19 and 20-29 correspond to the condition of Parkinson's Disease.
10. Claims 14, 19 and 20-29 correspond to the condition of Huntington's chorea.
11. Claims 14 and 20-29 correspond to the condition of cerebral palsy.
12. Claims 14 and 20-29 correspond to the condition of incontinence.
13. Claims 14 and 20-29 correspond to the condition of erectile dysfunction.
14. Claims 14 and 20-29 correspond to the condition of alopecia.

The following claim(s) are generic: none.

Art Unit: 1646

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the method of treatment of each condition can be performed independently of the other treatments. Each condition may require a substantially different method of treatment and require a significant search burden. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

A telephone call was made to Elizabeth J. Hecht on 5/12/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

Cileen B.O'Hara